NELAC Quality Systems Checklist



Organization Name:	
Address (Mailing):	
(Physical location)	
Telephone:	Facsimile:
E-mail:	Other:
Personnel Interviewed:	
Audit Location (if different):	
Audit Date:	Audit Organization:
Auditor(s):(Signatures)	
Receipt acknowledgment by Laboratory:	

Based on: Rev. 9, July 2, 1998 Page 1 of 60



Note:

If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. (5.1)

Delevient Aspect of Standards	Document Reference		Commonto
Relevant Aspect of Standards	NELAC	Lab	Comments
5.4 ORGANIZATION AND MANAGEMENT	•		
Is the laboratory legally identifiable?	5.4.1		
Is the laboratory organized and operated in such	5.4.1		
a way that its permanent, temporary and mobile			
facilities meet the requirements of this standard?			
Does the laboratory have managerial staff with	5.4.2.a		
the authority and resources needed to discharge			
their duties?			
Does the laboratory have a policy to ensure its	5.4.2.b		
personnel are free from any commercial, financial			
and other undue pressures, which might			
adversely affect the quality of the work?	5.4.0		
Is the laboratory organized in such a way that	5.4.2.c		
confidence in its independence of judgment and			
integrity is maintained at all times?	F 4 2 -		
Does the laboratory specify and document the	5.4.2.d,		
responsibility, authority, and interrelation of all	5.4.2.d.1, 5.4.2.d.2,		
personnel who manage, perform or verify work affecting the quality of calibrations and tests in job	5.4.2.u.z, 5.4.2.e,		
descriptions for all positions.	5.4.2.e, 5.5.2.f		
Do persons familiar with the calibration or test	5.4.2.e		
methods, procedures, and the objective of the	5.4.Z.E		
calibration or test and the assessment of the			
results provide supervision; is the responsibility			
proportioned such that adequate supervision is			
ensured?			
Do the technical director(s) (however named)	5.4.2.f		
have overall responsibility for the technical			
operation of the environmental testing laboratory?			
Do the technical director(s) of a laboratory	5.4.2.f,		
engaged in chemical analysis have a bachelors	4.1.1.1.a		
degree in chemical, environmental, biological			
sciences, physical sciences or engineering, with			
at least 24 college semester credit hours in			
chemistry and at least 2 years of experience in			
analysis for which accreditation is sought? (A			
masters or doctoral degree may be substituted for			
1 year experience)	<u>[</u>		

Based on: Rev. 9, July 2, 1998



Delayant Aspect of Clandards	Document I	Reference	Commonto
Relevant Aspect of Standards	NELAC	Lab	Comments
Do the technical director(s) of a laboratory limited to inorganic chemical analysis, other than metals analysis, have at least an associates degree in chemical, environmental, biological sciences, physical sciences or 2 years equivalent and successful college education, with at least 16 college semester credit hours in chemistry and at least 2 years of experience in analysis for which accreditation is sought?	5.4.2.f, 4.1.1.1.b		
Do the technical director(s) of a laboratory engaged in microbiological or biological analysis have a bachelors degree in microbiology, biology, chemical, environmental, physical sciences or engineering, with at least 16 college semester credit hours in general microbiology and biology and at least 2 years of experience in analysis for which accreditation is sought? (A masters or doctoral degree may be substituted for 1 year experience)	5.4.2.f, 4.1.1.1.c		
Do the technical director(s) of a laboratory engaged in chemical analysis have a bachelors degree in chemical, environmental, biological sciences, physical sciences or engineering, with at least 24 college semester credit hours in chemistry and at least 2 years of experience in analyses for which accreditation is sought? (A masters or doctorial degree may be substituted for 1 year experience)	5.4.2.f, 4.1.1.1.c		
Do the technical director(s) of a laboratory engaged in radiological analysis have a bachelors degree in chemistry, physics or engineering, with at least 24 college semester credit hours in chemistry and at least 2 years of experience in analysis for which accreditation is sought? (A masters or doctoral degree may be substituted for 1 year experience)	5.4.2.f, 4.1.1.1.d		

Based on: Rev. 9, July 2, 1998 Page 3 of 60



Delevent Aspect of Standards	Document Reference		Commonto
Relevant Aspect of Standards	NELAC	Lab	Comments
Do the technical director(s) of a laboratory engaged in the microscopic examination of asbestos and/or airborne fibers requiring the use of a transmission electron microscope have a bachelors degree, successful completion of courses in the use of the instrument, and one year experience (including identification of minerals), under supervision, in the use of the instrument.	5.4.2.f, 4.1.1.1.d.i		
Do the technical director(s) of a laboratory engaged in the microscopic examination of asbestos and/or airborne fibers requiring the use of a polarized light microscope have an associates degree or 2 years of college study, successful completion of formal course work in the use of the instrument, and one year experience (including identification of minerals), under supervision, in the use of the instrument.	5.4.2.f, 4.1.1.1.d.ii		
Do the technical director(s) of a laboratory engaged in the microscopic examination of asbestos and/or airborne fibers requiring the use of a phase contrast microscope, as in the determination of airborne fibers, have an associates degree or 2 years of college study, successful completion of formal course work in the use of the instrument, and one year experience	5.4.2.f, 4.1.1.1.d.iii		
Do the technical director(s) of a laboratory engaged in the examination of radon in air have an associates degree or 2 years of college study, and one year experience in radiation measurement including at least one year in the measurement of radon and/or radon progeny.	5.4.2.f, 4.1.1.1.d.f		
Does the quality assurance officer (however named) have responsibility for the quality system and its implementation?	5.4.2.g, 5.5.1.e		
Does the quality assurance officer have direct access to the highest level of management at which decisions are taken on laboratory policy or	5.4.2.g		

Based on: Rev. 9, July 2, 1998 Page 4 of 60



Deloyant Aspect of Standards	Document	Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
resources, and to the technical director?			
Does the quality assurance officer serve as the	5.4.2.g.1		
focal point for QA/QC and is responsible for the			
oversight and/or review of quality control data?			
Are the quality assurance officer functions	5.4.2.g.2		
independent from laboratory operations where			
quality assurance oversight is provided?			
Does the quality assurance officer evaluate data	5.4.2.g.3		
objectively and perform assessments without			
outside (e.g., managerial) influence?			
Does the quality assurance officer have	5.4.2.g.4		
documented training and/or experience in QA/QC			
procedures and knowledge of the quality system			
standard defined under NELAC?			
Does the quality assurance officer have a general	5.4.2.g.5,		
knowledge of the analytical methods for which	5.5.2.s		
data review is performed?			
Does the quality assurance officer arrange for or	5.4.2.g.6,		
conduct internal audits on the entire technical	5.4.2.g.7,		
operation annually, keep the quality manual	5.5.1.d,		
current, and notify laboratory management of	5.5.1.e,		
deficiencies in the quality system and monitor	5.5.2.s,		
corrective action?	5.5.3.1		
Does the laboratory nominate deputies in the	5.4.2.h		
case of absence of the technical director or			
quality assurance officer and have contingency			
plans in the event that either the technical director			
or quality assurance officer is absent?	5 1 2 i		
Does the laboratory have documented policies and procedures to ensure the protection of	5.4.2.i, 5.5.2.r		
clients' confidential information and proprietary	J.J.Z.I		
rights?			
Does the laboratory perform proficiency testing	5.4.2.j,		
two times per year per matrix per program from a	2.1.3,		
NELAC approved provider?	2.4.1		
5.5 QUALITY SYSTEM	<u>∠.</u> T. I		

Based on: Rev. 9, July 2, 1998 Page 5 of 60



Dolovant Acnost of Standards	Document Reference		Comments	
Relevant Aspect of Standards	NELAC	Lab	Comments	
Does the laboratory establish and maintain a	5.5.1,			
quality system appropriate to the type, range and	5.5.1.a			
volume of environmental testing activities it				
undertakes?				
Is the quality documentation available for use by	5.5.1.b,			
the laboratory personnel?	5.5.1.d			
Does the quality manual list the following:	5.5.2,			
Q Title page	5.5.2.f			
Q Document title				
Q Laboratory's full name and address				
Q The name, signature, address (if different				
from above), and telephone number of				
individual(s) responsible for the				
laboratory;				
Q The name and signature of the quality				
assurance officer (however named)				
Q The identification of all major				
organizational units covered by this				
quality manual				
Q Effective date of the version				
Does the quality manual and related quality	5.5.2.a,			
documentation include the objectives and	5.5.1.c			
commitments by top management?				
Does the quality manual and related quality	5.5.2.d			
documentation include procedures to ensure that				
all records required under NELAC are retained?				
Does the quality manual and related quality	5.5.2.d			
documentation include procedures for control and				
maintenance of documentation through a				
document control system which ensures that all				
standard operating procedures, manuals, or				
documents clearly indicate the time period during				
which the procedure or document was in force?				
Does the quality manual and related quality	5.5.2.g			
documentation include procedures for achieving				
traceability of measurements?				

Based on: Rev. 9, July 2, 1998 Page 6 of 60



Delevent Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Confinents
Does the quality manual and related quality documentation include a list of all methods under which the laboratory performs its accredited testing?	5.5.2.h		
Does the quality manual and related quality documentation include mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work?	5.5.2.i		
Does the quality manual and related quality documentation include reference to the calibration and/or verification test procedures used?	5.5.2.j		
Does the quality manual and related quality documentation include procedures for handling submitted samples?	5.5.2.k		
Does the quality manual and related quality documentation include reference to the major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests?	5.5.2.1		
Does the quality manual and related quality documentation include reference to procedures for calibration, verification and maintenance of equipment?	5.5.2.m		
Does the quality manual and related quality documentation include reference to verification practices including inter-laboratory comparisons, proficiency testing programs, use of reference materials, and internal quality control schemes?	5.5.2.n		
Does the quality manual and related quality documentation include procedures to be followed for feedback and corrective action for failed quality control samples, or when departures from documented policies, procedures, or NELAC standards occur?	5.5.2.o, 5.5.2.p		
Does the quality manual and related quality documentation include procedures for dealing with complaints?	5.5.2.q		

Based on: Rev. 9, July 2, 1998 Page 7 of 60



Relevant Aspect of Standards	Document I	Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Does the quality manual and related quality documentation include processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and/or receive any needed training?	5.4.2.f, 5.5.2.t		
Does the quality manual and related quality documentation include reference to procedures for reporting analytical results?	5.5.2.u		
Does the quality manual and related quality documentation include a Table of Contents, and applicable lists of references and glossaries, and appendices?	5.5.2.v		
Does the QAO or designee who are trained and qualified as auditors and independent of the activity being audited conduct internal audits?	5.5.3.1		
Is immediate corrective action taken when audit findings cast doubt on the correctness or validity of the calibrations or test results?	5.5.3.1		
Are clients notified immediately, in writing, when their work is affected by the findings from an internal audit?	5.5.3.1		
Is an annual review of the quality system completed by management to evaluate its continuing suitability and effectiveness and make any necessary changes or improvements?	5.5.3.2		
Are all audits and review findings and any corrective actions that arise from them documented?	5.5.3.3		
Does the quality assurance officer ensure that corrective actions are discharged within the agreed time scale?	5.5.3.3		

Based on: Rev. 9, July 2, 1998 Page 8 of 60



Delevient Aspect of Ctandards	Document I	Reference	Commonto
Relevant Aspect of Standards	NELAC	Lab	Comments
Does the laboratory implement checks to monitor the quality of laboratory results using internal quality control procedures (using statistical techniques whenever possible), participation in PT or other interlaboratory comparisons, use of reference material and/or in-house quality control using secondary reference materials, replicate testing, re-testing of retained samples, and correlation of results for different parameters of a sample.	5.5.3.4		
Are general procedures to determine when quality control data are out of control implemented in addition to providing acceptance criteria and specific protocols for corrective action in the method SOP?	5.5.3.5		
Are appropriate data qualifiers reported with samples associated with failed quality control measures?	5.5.3.5.b		
Are all quality control measures assessed and evaluated on an on-going basis, and quality control acceptance limits used to determine the usability of the data?	5.5.4.b		
Does the laboratory have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist?	5.5.4.c		
Are the quality control protocols specified by the laboratory's method manual followed?	5.5.4.d		
5.6 PERSONNEL			
Does the laboratory have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions?	5.6.1, 5.6.2, 5.6.3		
Are personnel responsible for complying with all quality assurance/quality control requirements that pertain to their organizational/technical function?	5.6.1		

Based on: Rev. 9, July 2, 1998 Page 9 of 60



Relevant Aspect of Standards	Document I	Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Does each technical staff member have a combination of experience and education to adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, analytical methods, quality assurance/quality control procedures and records management?	5.6.1		
Does the laboratory management maintain records to assure that all technical laboratory staff have demonstrated and documented initial and ongoing proficiency in the activities for which they are responsible?	5.6.2.b, 5.6.2.c		
Does the laboratory management assure all sample acceptance criteria (Section 5.11) are verified and that samples are logged into the sample tracking system and properly labeled and stored?	5.6.2.f		
Does the laboratory management ensure the production and quality of all data reported by the laboratory?	5.6.2.g		

Based on: Rev. 9, July 2, 1998 Page 10 of 60



Delevent Aspect of Standards	Document I	Reference	Comments	
Relevant Aspect of Standards	NELAC	Lab	Comments	
5.7 PHYSICAL FACILITIES	•			
Are the laboratory accommodations, test areas,	5.7.1.a			
energy sources, lighting, heating and ventilation				
adequate to facilitate proper performance of				
tests? Does the environment in which these activities	Г 7 1 h			
take place invalidate the results or adversely	5.7.1.b, 5.7.2.c			
affect the required accuracy of measurement?	5.7.2.0			
Particular care is taken when such activities are				
undertaken at sites other than the permanent				
laboratory premises.				
Are the facilities provided for the effective	5.5.4.a,			
monitoring, control and recording of	5.7.1.c			
environmental conditions, as appropriate? (Note:				
examples include biological sterility, dust,				
electromagnetic interference, humidity, main				
voltage, temperature, sound and vibration levels,				
as appropriate to the calibrations or tests				
concerned)	5.7.1.d			
In instances where monitoring or control of any of the above mentioned items are specified in a test	5.7.1.u			
method or by regulation, the laboratory shall meet				
and document adherence to the laboratory facility				
requirements				
Is there effective separation between neighboring	5.7.2.a,			
areas when the activities therein are	5.7.2.b, d			
incompatible? (including culture handling or				
incubation areas and volatile organic chemicals				
handling areas)				
5.8 EQUIPMENT AND REFERENCE MATERIALS				
Does the laboratory furnish all items of equipment	5.8.a			
(including reference materials) required for the				
correct performance of tests for which				
accreditation is sought?	E 0 o			
Is equipment outside the permanent control of the laboratory handled to ensure the requirements of	5.8.a			
the NELAC standard are met?				
THE INCLASTALINATE HIGT!				

Based on: Rev. 9, July 2, 1998 Page 11 of 60



Polov	vant Acrost of Standards	Document l	Reference	Comments
Kelev	vant Aspect of Standards	NELAC	Lab	Comments
	nt properly maintained, inspected	5.8.b		
and cleaned?				
	nce procedures documented?	5.8.b		
,	the equipment which has been	5.8.c		
	overloading or mishandling, or which			
	results, or has been shown by			
	otherwise to be defective, taken out			
	arly identified and wherever			
	d at a specified place until it has			
	and shown by calibration,			
	test to perform satisfactorily?	F 0 o		
	ratory examine the effect of this	5.8.c		
	vious calibrations or tests? If equipment including reference	5.8.d		
	eled, marked or otherwise identified	3.o.u		
	calibration status, when			
appropriate?	Calibration Status, when			
	t records include the following:	5.8.e.1 to 9		
	ame of the item of equipment	0.0.0.1 10 7		
	anufacturer's name, type			
	ication, and serial number or other			
	e identification			
	eceived and date placed in service			
	nt location, where appropriate			
	tion when received (e.g. new, used,			
	ditioned)			
	of the manufacturer's instructions,			
where	available			
Q Dates	and results of calibrations and/or			
	ations and date of the next			
	ation and/or verification			
	s of maintenance carried out to date			
	anned for the future			
	y of any damage, malfunction,			
	cation or repair			
5.9 MEAS	SUREMENT TRACEABILITY AND CA	ALIBRATION		

Based on: Rev. 9, July 2, 1998 Page 12 of 60



Delevent Aspect of Ctandards	Document Reference		Commonts
Relevant Aspect of Standards	NELAC	Lab	Comments
Are all measuring operations and testing equipment having an effect on the accuracy or validity of tests calibrated and/or verified before being put into service and on a continuing basis?	5.9.1		
Does the laboratory have an established program for the calibration and verification of its measuring and test equipment including balances, thermometers and control standards?	5.9.1		
Are reference standards of measurement held by the laboratory (such as Class S or equivalent weights or traceable thermometers) used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated?	5.9.3.a		
Is there a program of calibration and verification for reference standards?	5.9.3.b		
Are reference standards and measuring and testing equipment subject to in-service checks between calibrations and verifications, where relevant?	5.9.3.c		
Is all support equipment maintained in proper working order and records of all activities including service calls kept?	5.9.4.2.1.a		
Is all support equipment calibrated annually, using NIST traceable references when available, over the entire range in which the equipment is used?	5.9.4.2.1.b		
Are the results of support equipment calibration within the specifications required of the application for which it is used?	5.9.4.2.1.b		
Is support equipment removed from service until repaired or is a deviation curve prepared and all measurements corrected for the deviation when the calibration is not within acceptance limits?	5.9.4.2.1.b		
Are all measurements recorded and maintained for the deviation curve?	5.9.4.2.1.b		

Based on: Rev. 9, July 2, 1998 Page 13 of 60

Delevent Aspect of Standards	Polovant Aspect of Standards Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Prior to use on each working day, are balances, ovens, refrigerators, freezers, incubators and water baths checked with NIST traceable references (where possible) in the expected use range?	5.9.4.2.1.c		
Is additional monitoring as prescribed by the method performed for any device that is used in a critical test (such as incubators or water baths)?	5.9.4.2.1.c		
Is the acceptability for use or continued use according to to the needs of the analysis or application for which it is used?	5.9.4.2.1.c		
Are mechanical volumetric devices checked for accuracy on a monthly basis?	5.9.4.2.1.d		
Is the autoclave sterilization temperature and pressure of each run documented by the use of appropriate chemical or biological sterilization indicators (autoclave tape is not acceptable)?	5.9.4.2.2		
Is sterilization of each load demonstrated by use of a continuous recording device or with the use of spore strips?	5.9.4.2.2		
5.10 TEST METHODS AND SOPs	I =		
Does the laboratory document instructions on the use and operation of all relevant equipment, on the handling and preparation of samples and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests?	5.10.1.a		
Are all instructions, standards, manuals and reference data relevant to the work of the laboratory maintained up-to-date and readily available to the staff?	5.10.1.b		
Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, does the laboratory use documented procedures and appropriate techniques to obtain representative subsamples?	5.10.3		
Are calculations and data transfers subject to appropriate checks?	5.10.4		

Based on: Rev. 9, July 2, 1998 Page 14 of 60



Delevent Aspeat of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Does the laboratory establish Standard Operating Procedures to ensure that the reported data is free from transcription and calculation errors?	5.10.4.a		
Does the laboratory establish Standard Operating Procedures to ensure that all quality control measures are reviewed, and evaluated before data is reported?	5.10.4.b		
Do documented procedures exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory?	5.10.5		
Does the laboratory retain records, for all standards, including manufacturer/vendor, the manufacturer's Certificat of Analysis or purity (if supplied).	5.10.5.a		
Do records for all standards include the date of receipt, recommended storage conditions, and an expiration date after which the material shall not be used unless verified by the laboratory?	5.10.5.a		
Are original reagent containers labeled with the expiration date?	5.10.5.b		
Are detailed records maintained on reagent and standard preparation?	5.10.5.c		
Do the records indicate traceability to purchased stocks or neat compounds, and include the date of preparation and preparer's initials?	5.10.5.c		
Are all prepared reagents and standards uniquely identified and the contents clearly identified with preparation date, concentration(s) and preparer's initials?	5.10.5.d		
Does the laboratory ensure that all requirements of the NELAC Standard are complied with where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data?	5.10.6.a		

Based on: Rev. 9, July 2, 1998 Page 15 of 60

Delevent Aspect of Standards	Polovant Aspect of Standards Document Reference		Commente
Relevant Aspect of Standards	NELAC	Lab	Comments
Are Sections 8.1 through 8.11 of the EPA	5.10.6.a,		
Document "2185 - Good Automated Laboratory	5.12.1.g		
Practices" (1995), adopted as the standard for all			
laboratories employing microprocessors and			
computers?			
Is computer software documented and adequate	5.10.6.b		
for use?			
Are procedures established and implemented for	5.10.6.c		
protecting the integrity of data?			
Do the procedures include, but are not be limited	5.10.6.c		
to, integrity of data entry or capture, data storage,			
data transmission and data processing?			
Are computer and automated equipment	5.10.6.d		
maintained to ensure proper functioning and			
provided with the environmental and operating			
conditions necessary to maintain the integrity of			
calibration and test data?			
Does the laboratory establish and implement	5.10.6.e		
appropriate procedures for the maintenance of			
security of data including the prevention of			
unauthorized access to, and the unauthorized			
amendment of, computer records?			
5.11 SAMPLE HANDLING			
Does the laboratory have a documented system	5.11.1.a		
for uniquely identifying the items to be tested, to			
ensure that there can be no confusion regarding			
the identity of such items at any time?			
Does the system include identification for all	5.11.1.a		
samples, subsamples and subsequent extracts			
and/or digestates?			
Does the laboratory assign a unique identification	5.11.1.a		
(ID) code to each sample container received in			
the laboratory?			
Does the laboratory sample code maintain an	5.11.1.b		
unequivocal link with the unique field ID code			
assigned each container?			
Is the laboratory ID code placed on the sample	5.11.1.c		
container as a durable label?			

Based on: Rev. 9, July 2, 1998



Delevent Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Is the laboratory ID code entered into the laboratory records (see 5.11.3.d) and the link that associates the sample with related laboratory activities such as sample preparation or calibration?	5.11.1.d		
Does the laboratory have a a written sample acceptance policy that clearly outlines the circumstances under which samples will be accepted?	5.11.2		
Is data from any sample, which does not meet the policy criteria, flagged in an unambiguous manner clearly defining the nature and substance of the variation?	5.11.2		
Is the sample acceptance policy made available to sample collecting personnel and does it include at a minimum all the policy criteria?	5.11.2		
Does the sample acceptance policy criteria include the following at a minimum? Q Proper, full, and complete documentation, which includes sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample Q Proper sample labeling to include unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink Q Use of appropriate sample containers Q Adherence to specified holding times Q Adequate sample volume to perform the necessary tests. Q Procedures to be used when samples show signs of damage or contamination.	5.11.2. a to e		
Upon receipt, is the condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant test method, recorded?	5.11.3.a		

Based on: Rev. 9, July 2, 1998



Polovant Aspect of Standards Docu		Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Are all items specified in sample acceptance	5.11.3.a		
policy criteria checked?			
Are all samples, which require thermal	5.11.3.a.1		
preservation, considered acceptable if the arrival			
temperature is either within +/-2°C of the required			
temperature or the method specified range?	5.11.0		
For samples with a specified temperature of 4°C,	5.11.3.a.1,		
are samples maintained within a temperature of	5.11.4.a.1		
0.1 to 6°C?			
In cases where samples are hand delivered to the	5.11.3.a.1		
laboratory immediately after collection and do not			
meet the temperature criteria considered			
acceptable, is there evidence that the chilling			
process has begun such as arrival on ice?	F 44 0 0		
Does the laboratory implement procedures for	5.11.3.a.2		
checking chemical preservation using readily			
available techniques, such as pH, free chlorine or			
temperature, prior to or during sample preparation			
or analysis?	E 11 2 h		
Are the results of all checks recorded?	5.11.3.b		
Where there is any doubt as to the item's	5.11.3.c		
suitability for testing, where the sample does not			
conform to the description provided, or where the			
test required is not fully specified, does the			
laboratory consult with the client for further			
instruction before proceeding.			

Based on: Rev. 9, July 2, 1998 Page 18 of 60



Polovant Acnost of Standards	Relevant Aspect of Standards Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
If the sample does not meet the sample receipt	5.11.3.c.1 to		
acceptance criteria does the laboratory do any of	2		
the following: • Q Retain correspondence and/or records of			
conversations concerning the final			
disposition of rejected			
Q Fully document any decision to proceed			
with the analysis of samples not meeting			
acceptance criteria			
i. Is the condition of these samples, at a minimum,			
noted on the chain of			
custody or transmittal			
form and laboratory			
receipt documents?			
ii Is the analysis data			
appropriately "qualified" on the final report?			
Does the laboratory utilize a permanent,	5.11.3.d		
sequential log, such as a logbook or electronic	0.11.0.u		
record, to document receipt of all sample			
containers?			
Is the following information recorded in the	5.11.3.d.1.i		
laboratory chronological log?	through iv.		
Q Client/Project NameQ Date and time of laboratory receipt of			
sample			
Q Unique laboratory ID code (see 5.11.1)			
Q Signature or initials of data logger			

Based on: Rev. 9, July 2, 1998 Page 19 of 60

Relevant Aspect of Standards Document Reference		Comments	
Note valit Aspect of Standards	NELAC	Lab	Comments
Is the following information unequivocally linked to the log in records, included as a part of the log, or if recorded/documented elsewhere is it a part of the laboratory's permanent records, easily retrievable upon request and readily available to individuals who will process the sample? Q Field ID code linked to laboratory ID code in the sample receipt log. Q Date and time of sample collection linked to the sample container and to the date and time received in the laboratory. Q Requested analyses (including applicable approved test method numbers) linked to the laboratory ID code. Q Any comments resulting from inspection for sample rejection linked to the	5.11.3.d.2.i through iv.		
laboratory ID code. Is all documentation, such as memos or transmittal forms that are transmitted to the laboratory by the sample transmitter retained?	5.11.3.e		
Is a complete chain of custody record (Section 5.12.4), if utilized, maintained?	5.11.3.f		
Does the laboratory have documented procedures and appropriate facilities to avoid deterioration or damage to the sample, during storage, handling, preparation, and testing	5.11.4		
Are any relevant instructions provided with the a sample followed?	5.11.4		
Where items have to be stored or conditioned under specific environmental conditions, are these conditions maintained, monitored and recorded where necessary?	5.11.4		
Are samples stored away from all standards, reagents, food and other potentially contaminating sources?	5.11.4.a.2		
Are samples, sample fractions, extracts, leachates or other sample preparation fractions stored according to the conditions specified by preservation protocols?	5.11.4.b		

Based on: Rev. 9, July 2, 1998 Page 20 of 60



Delevent Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Where a sample or portion of the sample is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), does the laboratory have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned?	5.11.4.c		
Does the laboratory have standard operating procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products, including all provisions necessary to protect the integrity of the laboratory?	5.11.5		
5.12 RECORDS	I = 10		
Does the laboratory maintain a record system to suit its particular circumstances and comply with any applicable regulations?	5.12		
Does the system produce unequivocal, accurate records, which document all laboratory activities?	5.12		
Does the laboratory retain on record all original observations, calculations and derived data, calibration records and a copy of the test report for an appropriate period?	5.12		
Does the record keeping system allow historical reconstruction of all laboratory activities that produced the resultant sample analytical data?	5.12.1		
Is the history of the sample readily understood through the documentation including interlaboratory transfers of samples and/or extracts?	5.12.1		
Do the records include the identity of personnel involved in sampling, preparation, calibration or testing?	5.12.1.a		
Is all information relating to the laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification documented?	5.12.1.b		

Based on: Rev. 9, July 2, 1998 Page 21 of 60



Polovant Aspect of Standards Document Referer		Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Does the record keeping system facilitate the	5.12.1.c		
retrieval of all working files and archived records			
for inspection and verification purposes?			
Are all documentation entries signed or initialed	5.12.1.d		
by responsible staff with labels indicating the			
reason for the signature or initial clearly indicated in the records?			
Are all generated data except those that are	5.12.1.e		
generated by automated data collection systems	5.12.1.e		
recorded directly, promptly and legibly in			
permanent ink?			
Are entries in records not obliterated by methods	5.12.1.f		
such as erasures, overwritten files or markings?			
Are all corrections to record-keeping errors made	5.12.1.f		
by one line marked through the error and the			
individual making the correction signing (or			
initialing) and dating the correction?			
Are all records, certificates and reports held	5.12.2.a		
secure and in confidence to the client?	F 10.0		
Are NELAP related records available to the	5.12.2.a		
accrediting authority?	F 10 0 b		
Are all records (including the hardware and software necessary for the historical	5.12.2.b		
reconstruction of electronic data) that are			
pertinent to a specified project retained for a			
minimum of five years unless otherwise			
designated for a longer period of time in another			
regulation?			
Do records that are stored or generated by	5.12.2.c		
computers or personal computers (PCs) have			
hard copy or write-protected backup copies?			
Does the laboratory have a record management	5.12.2.d		
system for control of laboratory notebooks;			
instrument logbooks; standards logbooks; and			
records for data reduction, validation storage and			
reporting?	F 10 0		
Is access to archived information documented	5.12.2.e		
with an access log?			

Based on: Rev. 9, July 2, 1998 Page 22 of 60



Deloyant Acnost of Standards	Document I	Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Is archieved information protected against fire, theft, loss, environmental deterioration, and vermin and, in the case of electronic records, electronic or magnetic sources?	5.12.2.e		
Does the laboratory have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that a laboratory transfers ownership or goes out of business,?	5.12.2.f		
Do strip charts, tabular printouts, computer data files, analytical notebooks, and run logs include: Q Laboratory sample ID code Q Date of analysis Q Instrumentation identification and instrument operating conditions/parameters (or reference to such data) Q Analysis type Q All calculations (automated and manual) Q Analyst's or operator's initials/signature	5.12.3.3. a to f		
 Are the following administrative records maintained? Q Personnel qualifications, experience and training records Q Initial and continuing demonstration of proficiency for each analyst Q A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record 	5.12.3.4. a to c		
Do the legal COC records account for all time periods associated with the samples?	5.12.4.1.b		
Do the legal COC records include signatures of all individuals who physicall handled individual samples?	5.12.4.1.c 5.12.4.2.b		

Based on: Rev. 9, July 2, 1998 Page 23 of 60



Polovant Aspect of Standards Document Reference		Comments	
Relevant Aspect of Standards	NELAC	Lab	Comments
After receipt for legal COC, are laboratory personnel: (1) responsible for the care and custody of the sample and (2) prepared to testify that the sample was in their possession and view or secured in the laboratory at all times from the moment it was received from the custodian until the time that the analyses are completed or the sample is disposed?	5.12.4.k		
Do tracking records for legal COC include the time of day and calendar date of each transfer or handling procedure?	5.12.4.2.a		
Do tracking records for legal COC include all information necessary to produce unequivocal, accurate records that document the laboratory activities associated with sample receipt, preparation, analysis and reporting?	5.12.4.2.c		
Do tracking records for legal COC include common carrier documents?	5.12.4.d		
Is access to all legal samples and subsamples controlled and documented?	5.12.4.3		
Is a clean, dry, isolated room, building, and/or refrigerated space that can be securely locked from the outside designated as a custody room?	5.12.4.3.a		
Where possible, is distribution of samples to the analyst performing the analysis made by the custodian(s)?	5.12.4.3.b		
Is the laboratory area maintained as a secured area, restricted to authorized personnel only?	5.12.4.3.c		
Once the sample analyses are completed, is the unused portion of the sample, together with all identifying labels, returned to the custodian?	5.12.4.3.d		
Is the returned tagged sample retained in the custody room until permission to destroy the sample is received by the custodian or other authority?	5.12.4.3.d		
Is transfer of samples, subsamples, digestates or extracts to another party subject to all of the requirements for legal chain of custody?	5.12.4.4		

Based on: Rev. 9, July 2, 1998 Page 24 of 60



Relevant Aspect of Standards	Document I	Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Confinents
If the sample is part of litigation, does disposal of	5.12.4.5.a		
the physical sample occur only with the			
concurrence of the affected legal authority,			
sample data user and/or submitter of the sample?			
Are all conditions of disposal and all	5.12.4.5.b		
correspondence between all parties concerning			
the final disposition of the physical sample			
recorded and retained?			
Do records indicate the date of disposal, the	5.12.4.5.c		
nature of disposal (such as sample depleted,			
sample disposed in hazardous waste facility or			
sample returned to client), and the name of the			
individual who performed the task?			
5.13 REPORTS		•	

Based on: Rev. 9, July 2, 1998 Page 25 of 60



	Relevant Aspect of Standards	Document I	Reference	Comments
	Relevant Aspect of Standards	NELAC	Lab	Comments
Does	he report contain:	5.13.a. 1 to		
Q	A title	7		
Q	Name/address of laboratory			
Q	Location where analysis is carried out if different			
Q	Phone number and contact name			
Q	Unique identification of the certificate or			
	report and the pages are identified in a			
	way that it is clear to the reader that the			
	report contains a specific number of			
	pages.			
Q	Name and address of client, where			
	appropriate and project name if applicable			
Q	Description and unambiguous			
	identification of the tested sample including the client identification code			
Q	Identification of results derived from			
۷	samples that did not meet NELAC			
	acceptance requirements such as			
	improper container, holding time, or			
	temperature.			
Q	Date of receipt of sample, date and time of			
	sample collection, date(s) of performance			
	test, and time of sample preparation			
	and/or analysis if the required holding time			
	for either activity is less than or equal to			
	48 hours			

Based on: Rev. 9, July 2, 1998 Page 26 of 60



	Delevent Aspect of Standards	Document I	Reference	Comments
	Relevant Aspect of Standards	NELAC	Lab	Confinents
	he report contain:	5.13.a. 8 to		
Q	Identification of the test method used, or	16		
	unambiguous description of any non-			
	standard method used			
Q	If the laboratory collected the sample,			
	reference to sampling procedure			
Q	Any deviations from, additions to or exclusions from the test method, and any			
	other information relevant to a specific			
	test, such as environmental conditions			
	including the use of relevant data			
	qualifiers and their meaning			
Q	Measurements, examinations and derived			
	results, supported by tables, graphs,			
	sketches and photographs as appropriate,			
	and any failures (such as failed quality			
	control) identified			
Q	Identify whether data are calculated on			
	dry weight or wet waight, reporting units,			
	and for Whole Effluent Toxicity, the			
	statistical package used to provide the data.			
Q	When required, a statement of the			
9	estimated uncertainty of the test result.			
Q	A signature and title, or an equivalent			
	electronic identification of the person(s)			
	accepting responsibility for the content of			
	the certificate or report (however			
	produced), and date of issue			
Q	Where relevant, a statement to the effect			
	that the results relate only to the items			
	tested or to the sample as received by the			
_	laboratory Where relevant, a statement that the			
Q	certificate or report shall not be			
	reproduced except in full, without the			
	written approval of the laboratory			
Q	Where relevant, clear identification of all			
	data provided by outside sources, such as			

Based on: Rev. 9, July 2, 1998 Page 27 of 60



Delevent Aspeat of Standards	Document I	Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Does the report contain: Q Where relevant, clear indication of numberical results with values below 3.18 times the MDL	5.13.a.17		
Are all applicable elements in 5.13.a.1 through 17 readily available for review if not issued in a formal report by an in-house or captive laboratory?	5.13.b, 5.13.b.1		
Are all applicable elements in 5.13.a.1 through 17 provided to another individual within the organization for preparation of regulatory reports?	5.13.b.2		
Does the facility management ensure that the appropriate report items are in the report to the regulatory authority if the report is prepared by another individual within the organization.	5.13.b.2		
Where the certificate or report contains results of tests performed by sub-contractors, are these results clearly identified by subcontractor name or applicable accreditation number?	5.13.c		
After issuance of the report, does the laboratory report remain unchanged?	5.13.d		
Are material amendments to a calibration certificate, test report or test certificate after issue made only in the form of a further document, or data transfer including the statement "Supplement to Test Report or Test Certificate, serial number [or as otherwise identified]", or equivalent form of wording?	5.13.d		
Do amendments to the formal report meet all the relevant requirements of this Standard?	5.13.d		
Does the laboratory notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate?	5.13.e		

Based on: Rev. 9, July 2, 1998 Page 28 of 60



Relevant Aspect of Standards	Document I	Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Confinents
Does the laboratory ensure that, where clients require transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, that staff follows documented procedures that ensure that the requirements of this Standard are met and that confidentiality is preserved?	5.13.f		
Does the laboratory certify that the test results meet all requirements of NELAC or provide reasons and/or justification if they do not?	5.13.g		
5.14 SUBCONTRACTING			
Does the laboratory have records to indicate that it advisse the client in writing of its intention to sub-contract any portion of the testing to another party?	5.14.a, 5.14.c		
Where a laboratory sub-contracts any part of the testing covered under NELAP, records indicate that this work is placed with a laboratory accredited under NELAP for the tests to be performed?	5.14.b, 5.14.c		

Based on: Rev. 9, July 2, 1998 Page 29 of 60



Deleviant Aspect of Standards	Document I	Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
5.15 SERVICES AND SUPPLIES			
Where the laboratory procures outside services and supplies, other than those referred to in this Standard, in support of tests, does the laboratory use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's tests?	5.15.a		
Where no independent assurance of the quality of outside support services or supplies is available, does the laboratory have procedures to ensure that purchased equipment, materials and services comply with specified requirements? (Note: The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.)	5.15.b		
Does the laboratory maintain records of all suppliers from whom it obtains support services or supplies required for tests?	5.15.c		
5.16 COMPLIANTS			
Does the laboratory have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities?	5.16		
Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this Standard or otherwise concerning the quality of the laboratory's calibrations or tests, does the laboratory ensure that those areas of activity and responsibility involved are promptly audited in accordance with Section 5.5.3.1?	5.16		
Are records of the complaint and subsequent actions maintained?	5.16		

Based on: Rev. 9, July 2, 1998 Page 30 of 60



Delevent Aspeat of Standards	Document I	Reference	Comments			
Relevant Aspect of Standards	NELAC	Lab	Comments			
5. APPENDIX C - Demonstration of Capability Certificate						
Are initial demonstrations, continuing demonstrations and method certification documented through the use of the forms in the latest approved NELAC document Appendix C?	C.1					
Is the QC sample used for the IDC, purchased from an outside source, or if not available is the QC sample prepared by the laboratory independent of the instrument calibration standards?	C.1.a					
Is the concentrate of the QC sample diluted in a volume of clean matrix sufficient to prepare four aliquots at the required method volume to a concentration approximately 10 times the method-stated or laboratory-calculated method detection limit?	C.1.b					
Are four aliquots prepared and analyzed according to the method either concurrently or over a period of days?	C.1.c					
Is the average recovery and standard deviation for each parameter of interest calculated in the units used for reporting (such as mg/L)?	C.1.d					
Does the average recovery and standard deviation meet the acceptance criteria for the method (either reference or laboratory generated limits if a non-standard method is performed)?	C.1.e					
Is the problem corrected followed by repeated analysis of the four aliquots?	C.1.f					
Is a copy of the initial demonstration of Capability Certificate (IDC) in the personnel records for each employee performing a test method?	C.2					

Based on: Rev. 9, July 2, 1998 Page 31 of 60



Delayant Aspect of Claudands	Document I	Reference	Commonto
Relevant Aspect of Standards	NELAC	Lab	Comments
Does the certification statement include the following wording: "1. The analysts identified above, using the cited method, which is in use at this facility for the analyses of samples under the National Environmental Laboratory Accreditation Program, have met the Initial Demonstration of Capability.	C.2		
2. The method was performed by the analyst(s) identified on this certification.			
3. A copy of the method and the laboratory- specific SOPs are available for all personnel on- site.			
4. The data associated with the initial demonstration capability are true, accurate, complete and self-explanatory (1).			
5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized inspectors."			
5. APPENDIX D - Chemical Testing and Air	Testing Deta	iled Method	Review
For air testing, the blank and laboratory control san used when feasible. Method Number: SOP Number: Rev.:	nple shall be u	sed. Matrix s	spikes and duplicates shall be
SOP date: Personnel records observed:			
Data records observed:			
For air testing, is a desorption efficiency determined as appropriate?	D.5		
Is the method followed as specified in the methods manual?	D.1.1		

Based on: Rev. 9, July 2, 1998 Page 32 of 60



Relevant Aspect of Standards	Document I	Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Does the laboratory maintain standard operating	D.1.1,		
procedures (SOPs) that accurately reflect all	5.10.1.1		
phases of current laboratory activities such as			
assessing data integrity, corrective actions,			
handling customer complaints, and all test			
methods?	D 4 4		
If the test methods used are copies of published	D.1.1,		
methods are any changes in the methods	5.10.1.1.b,		
documented and included in the methods manual	5.10.1.2.b		
Are copies of all SOPs accessible to all	D.1.1,		
personnel?	5.10.1.1.c		
Are the SOPs logically organized and include the	D.1.1,		
signature(s) of the approving authority?	5.10.1.1.d,		
	5.10.1.1.e		
Does each SOP clearly indicate the effective date	D.1.1,		
of the document, and the revision number?	5.10.1.1.e		
Does the laboratory have and maintain an in-	D.1.1,		
house methods manual(s) for each accredited	5.10.1.2.a		
analyte or test?			

Based on: Rev. 9, July 2, 1998 Page 33 of 60



Relevant Aspect of Standards NELAC Does each method include or reference where applicable: Q Identification of the test method and where applicable, the analyte name with qualifier (the qualifier is a word, phrase or number that better identifies the method; e.g., "Iron, Total", or "Chloride, Automated Comments D.1.1, 5.10.1.2.b		Delevant Aspect of Standards	Document Reference		Comments
applicable: Q Identification of the test method and where applicable, the analyte name with qualifier (the qualifier is a word, phrase or number that better identifies the method; e.g.,		Relevant Aspect of Standards	NELAC	Lab	Comments
Q Identification of the test method and where applicable, the analyte name with qualifier (the qualifier is a word, phrase or number that better identifies the method; e.g.,	Does	each method include or reference where			
applicable, the analyte name with qualifier (the qualifier is a word, phrase or number that better identifies the method; e.g.,	applica		5.10.1.2.b		
(the qualifier is a word, phrase or number that better identifies the method; e.g.,	Q				
that better identifies the method; e.g.,					
, and the second		•			
"Iron, Total", or "Chloride, Automated"		· · · · · · · · · · · · · · · · · · ·			
Figure 2 delle collo de de Malle d COD					
Ferricyanide", or "Our Lab. Method SOP					
No. 101")		,			
Q Applicable matrix or matrices	_				
Q Method detection limit					
Q Scope and application					
Q Summary of the methodQ Definitions					
Q Interferences					
Q Safety					
Q Equipment and supplies		3			
Q Reagents and standards					
Q Sample collection, preservation, shipment		· ·			
and storage		· · · · · · · · · · · · · · · · · · ·			
Q Quality control	Q	<u> </u>			
Q Calibration and standardization	Q				
Q Procedure	Q	Procedure			
Q Calculations	Q	Calculations			
Q Method performance	Q	Method performance			
Q Pollution prevention	Q				
Q Data assessment and acceptance criteria	Q	•			
for quality control measures	_				
Q Corrective actions for out-of-control data					
Q Contingencies for handling out-of-control	Q				
or unacceptable data		•			
Q Waste management	_	· · · · · · · · · · · · · · · · · · ·			
Q References					
Q Any tables, diagrams, flowcharts and validation data	u				
Are the method and procedures consistent with D.1.1,	Aro th		D 1 1		
the accuracy required, and with any standard 5.10.2.a		•	· ·		
specifications relevant to the calibrations or tests			J. 10.2.a		
concerned?					

Based on: Rev. 9, July 2, 1998 Page 34 of 60



Delevent Aspect of Standards	Document I	Reference	Commonto
Relevant Aspect of Standards	NELAC	Lab	Comments
When the use of mandated methods for a sample	D.1.1,		
matrix is required, are only those methods used?	5.10.2.a.1		
Where methods are employed that are not	D.1.1,		
required, as in the Performance Based	5.10.2.a.2		
Measurement System approach, are the methods			
fully documented and validated (see 5.10.2.1),			
and available to the client and other recipients of			
the relevant reports?	D 1 1		
Prior to acceptance and institution of any method,	D.1.1, 5.10.2.1.a		
is satisfactory initial demonstration of method performance achieved	5.10.2.1.a		
Is satisfactory continuing demonstration of	D.1.1,		
method performance (such as laboratory control	5.10.2.1.b		
samples) achieved as required?	J. 10.2.1.b		
In all cases, are the appropriate forms such as	D.1.1,		
the Certification Statement (Appendix C) or	5.10.2.1.a.1		
standard performance checklists (see Appendix	5.10.2.1.a.2		
E) completed and retained by the laboratory and	5.10.2.1.b		
made available upon request?			
Are all associated supporting data necessary to	D.1.1,		
reproduce the analytical results summarized in	5.10.2.1.c		
the checklists retained by the laboratory?			
Is initial demonstration of method performance	D.1.1,		
completed each time there is a significant change	5.10.2.1.d		
in instrument type, personnel or method?	D 1 1 -		
Is a method blank performed 1 per batch, per	D.1.1.a,		
matrix type per preparation method?	5.5.4.a D.1.1.a.1.i		
Is the souce of contamination investigated and corrective action taken if the blank contamination	D.1.1.a.1.1		
greater than 1/10th of the measured			
concentration of any sample in the associated			
sample batch and less than 1/10th of the			
regulatory limit?			
Is the analysis stopped, corrected and the	D.1.1.a.1.ii		
problem eliminated if the blank contamination is			
greater than 1/10th of the measured sample			
contamination or 1/10th of the regulatory limit?			

Based on: Rev. 9, July 2, 1998 Page 35 of 60



Delevent Aspect of Standards	Document	Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Are samples associated with the contaminated	D.1.1.a.1		
blank reprocessed for analysis or the results			
reported with appropriate data qualifying codes?			
Is a laboratory control sample (LCS) performed at	D.1.1.b.1,		
a frequency of 1 in 20 samples per matrix, per	5.5.4.a		
sample extraction or preparation method?			
If the matrix spike is used as the LCS, is the	D.1.1.b.1		
acceptance criteria as stringent as the LCS?			
Is the LCS used for determining batch	D.1.1.b.1		
acceptance?			
Is a matrix spike (MS) performed at a frequency	D.1.1.b.2,		
of 1 in 20 samples per matrix, per sample	5.5.4.a		
extraction or preparation method?			
Is the sample selected as the matrix spike rotated	D.1.1.b.2		
among clients?			
Are problems with the matrix spike reported to the	D.1.1.b.2		
client whose sample was used for the spike?			
Are surrogate compounds added to all samples,	D.1.1.b.3		
standards, and blanks, whenever possible, for all			
organic chromatography methods?			
If the method does not specify the spiking	D.1.1.b.4		
compounds, does the laboratory spike include all			
reportable components in the LCS and MS?			
For long lists or incompatible components are a	D.1.1.b.4		
representative number (10%) of the listed			
components used to control the method?			
Are the selected components of each spiking mix	D.1.1.b.4		
representative of all chemistries, elution patterns			
and masses and includes permit specified			
analytes and other client requested components?	D 4 4 1 . 4		
Does the laboratory ensure, that all reported	D.1.1.b.4		
components are used in the spike mixture within			
a two-year time period, and that no one			
component or components dominate the spike			
mixture?	D 1 2		
Is a matrix spike duplicate (MSD) or laboratory	D.1.2,		
duplicates performed at a frequency of 1 in 20	5.5.4.a		
samples per matrix, per sample extraction or			
preparation method?			

Based on: Rev. 9, July 2, 1998



Delevent Aspect of Standards	Appeat of Standards Document Reference		Commonto
Relevant Aspect of Standards	NELAC	Lab	Comments
Is the sample selected as the duplicates rotated	D.1.2		
among clients?			
Are problems with the duplicates reported to the	D.1.2		
client whose sample was used for the spike?			
Is the Initial Demonstration of Capability forms	D.1.3.a,		
found in Appendix C completed prior to method	4.5.4.a		
acceptance and with any significant change to	5.10.2.1		
instrument type, personnel or method for			
mandated or EPA methods?			
Is the overall program of calibration and/or	D.1.3.d,		
verification and validation of equipment designed	5.9.2.a		
and operated to ensure, wherever applicable,			
measurements made by the laboratory are			
traceable to national standards of measurement			
where available?			
Do calibration certificates, wherever applicable,	D.1.3.d,		
indicate the traceability to national standards of	5.9.2.b, 5.9.		
measurement and provide the measurement			
results and associated uncertainty of			
measurement and/or a statement of compliance			
with an identified metrological specification?			
Is each calibration dated and labeled with	D.1.3.d,		
method, instrument, analysis date, and each	5.9.4.1.a		
analyte name, concentration and response (or			
response factor)?			
Are the axes of the calibration curve labeled when	D.1.3.d,		
used?	5.9.4.1.b		
Is the equation for the curve and the correlation	D.1.3.d,		
coefficient recorded when electronic data	5.9.4.1.b		
processing systems automatically compute the			
calibration curve?	D 4 0 1		
Is the equation for the line and the correlation	D.1.3.d,		
coefficient recorded when the calibration curve is	5.9.4.1.b		
prepared manually?	D 1 2 1		
Is a criterion for the acceptance of a calibration	D.1.3.d,		
curve established and documented? (Note: an	5.9.4.1.c		
example is an acceptable correlation coefficient)			

Based on: Rev. 9, July 2, 1998 Page 37 of 60



Relevant Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Is the method specified criteria met for the acceptance of a calibration curve when	D.1.3.d, 5.9.4.1.c		
applicable? Are all initial calibrations verified with a standard obtained from a second or different source, where available?	5.9.4.3.a		
Is the verification standard analyzed with each initial calibration and found to be within 15% of the true value unless the laboratory can demonstrate through historical data that wider limits are applicable?	5.9.4.3.a		
Are the calibration curves prepared as specified in the method?	5.9.4.3.b		

Based on: Rev. 9, July 2, 1998 Page 38 of 60



Deloyant Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Confinents
Does the laboratory establish the appropriate number of standards for use in the initial calibration using the following: Q Is the percent relative standard deviation (%RSD) determined by: Q Taking at least seven replicate measurements of a standard with a concentration approaching the lowest quantitation level or Q Performing a calibration linearity test (such as response factor or calibration factor) on at least 3 standards having concentrations that cover the expected calibration range. Q Is the minimum number of standards to be used in the initial calibration dependent on the resulting %RSD %RSD Number of Calibration Points 0 - < 2 1 ** 2 - < 10 3 10 - < 25 5 > 25 7 **Assumes linearity through the origin (0.0). For analytes for which there is no origin (such as pH), a two-point calibration curve shall be used. Q If the resulting curve is non-linear, are additional standards used? Q Is the number of standards as determined from the above table and a blank used for the initial calibration curve subject to a calibration	NELAC 5.9.4.3.b	Lab	
Is the calibration curve subject to a calibration linearity test, such as a linear regression or percent RSD of response factors (internal standard calibration) or calibration factors (external standard calibration) in addition to the	5.9.4.3.c		
verification by second-source standards?			

Based on: Rev. 9, July 2, 1998 Page 39 of 60



Delevent Aspect of Standards	Document F	Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Confinents
Are the sample results bracketed by calibration standards under all circumstances? (Note: For calibrations employing a single calibration point, the level in the blank or zero (whichever is applicable) is assumed to be the low calibration point. For those situations where the result will be used in a decision related to the determination of a non-occurrence or "non-detect" (ND) of an	D.1.3.b 5.9.4.3.d		
analyte, the standard shall be at 1 - 5 times the quantitation limit of the method.) When not included in the analytical method, is the	D.1.3.b		
value of the analyte(s) in the calibration verification standards within 15% of the true value unless the laboratory can demonstrate through historical data that wider limits are applicable?	5.9.4.4		
When an initial calibration curve is not run on the day of analysis, is the integrity of the initial calibration curve verified on each day of use (or 24 hour period) by initially analyzing a blank and a standard at the method defined concentration or a mid-level concentration if not included in the method?	D.1.3.b 5.9.4.4.1.a		
If the initial calibration verification fails, is the analysis procedure stopped and evaluated?	D.1.3.b 5.9.4.4.1.b		
In all cases, is the initial calibration verification acceptable before analyzing any samples?	D.1.3.b 5.9.4.4.1.b		
Are additional standards analyzed after the initial calibration curve or is the integrity of the initial calibration curve accepted? (For more details refer to 5.9.4.3.a or 5.9.4.4.1)	D.1.3.b 5.9.4.4.2		
Are the continuing calibration standards analyzed at a frequency of 5% or every 12 hours whichever is more frequent? (Note: the standards may be those used in the original calibration curve or standards from another source.)	D.1.3.b 5.9.4.4.2.a		
Is the frequency of analyzing continuing calibration standards increased if the instrument consistently drifts outside acceptable limits before the next calibration?	D.1.3.b 5.9.4.4.2.a		



Relevant Aspect of Standards	Document Reference		
Note valid Aspect of Standards	NELAC	Lab	Comments
Is the concentration of continuing calibration standards determined by the anticipated or known concentration of the samples and/or method specified levels?	D.1.3.b 5.9.4.4.2.b		
Is at least one standard at a low-level concentration?	D.1.3.b 5.9.4.4.2.b		
To the extent possible, are the samples in each interval (i.e. every 20 samples or every 12 hours) bracketed with standard concentrations closely representing the lower and upper range of reported sample concentrations. (Note: If this is not possible, the standard calibration checks should vary in concentration throughout the range of the data being acquired.)	D.1.3.b 5.9.4.4.2.b		
Is a new curve run if two back-to-back runs of one continuing calibration checks are outside acceptable limits?	D.1.3.b 5.9.4.4.2.c		
When the continuing calibration check limit is exceeded high (i.e., high bias), and there are non-detects for the corresponding analyte in all environmental samples associated with the continuing calibration check, are the non-detects reported, and the other samples affected by the unacceptable check reanalyzed after a new calibration curve has been established, evaluated and accepted? (Note: Additional sample analysis shall not occur until a new calibration curve is established and verified.)	D.1.3.b 5.9.4.4.2.c		
Are proficiency samples used by the laboratory to evaluate the ability of the laboratory to produce accurate data?	D.1.3.c		
Are method detection limits determined by 40 CFR Part 136 unlessincluded in a method or program? (MDL studies are not required for any component for which a spiking solution is not available).	D.1.4.a		
Is the MDL determined initially for the compounds of interest in a clean matrix such as lab pure water or Ottawa sand or the matrix of interest?	D.1.4.b		



Delevent Aspect of Standards	Document Reference		Commonto
Relevant Aspect of Standards	NELAC	Lab	Comments
Are qualitatively reported results (those greater than 3.18 times the MDL) bracketed by calibration or calibration verification standards.	D.1.4.c		
Is the MDL verified annually by the preparation and analysis of at least one clean matrix sample spiked at the current reported MDL?	D.1.4.d		
If the MDL is not verified, is the MDL study repeated to establish a new MDL?	D.1.4.d		
Are all procedures documented, including the matrix type?	D.1.4.e		
Are procedures for data reduction, such as use of linear regression, documented?	D.1.5		
Is the source of standards traceable to national standards or proven through inter-laboratory studies? (See 5.9.2 for details)	D.1.6.a		
In methods where the purity of reagents is not specified, is analytical reagent grade used?	D.1.6.b.1		
Is the container labeling documented to verify that the purity of the reagents meets the requirements of the particular method?	D.1.6.b.1		
Is the quality of water sources monitored and documented to meet method specified requirements?	D.1.6.b.2		
Does the laboratory develop and document acceptance criteria for retention time windows? Note: Absolute retention time and relative retention time aid in the identification of components in chromatographic analyses and to evaluate the effectiveness of a column to separate constituents	D.1.7.a		
Is confirmation documented and performed to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory for organic tests such as pesticides, herbicides, or acid extractable or when recommended by the analytical method? Note: Confirmation is not required when the analysis involves the use of a mass spectrometer.	D.1.7.b		



Delevent Aspect of Clandards	Document I	Reference	Commonto
Relevant Aspect of Standards	NELAC	Lab	Comments
If confirmation not performed, is it based on client written stipulation?	D.1.7.b		
Does the laboratory develop and document acceptance criteria for mass spectral tuning?	D.1.7.c		
Does the laboratory assure that the test instruments consistently operate within the specifications of the test methods and equipment manufacturer?	D.1.8.a		
Is glassware cleaned to meet the sensitivity of method?	D.1.8.b		
Are all cleaning and storage procedures that are not specified by the method documented in laboratory records and SOPs?	D.1.8.b		
5. APPENDIX D - Whole Effluent Testing Detail	ed Method Re	view	
Method Number: SOP Number: Rev.: SOP date: Personnel records observed: Data records observed:			
Does the laboratory demonstrate its ability to obtain consistent results with reference toxicants before it performs toxicity tests with effluents for permit			
compliance purposes? Does the laboratory maintain control charts for the control performance and reference toxicant statistical endpoint (such as NOEC or ECp)?	D.2.1.a.1.i		
Does the laboratory evaluate the intra-laboratory variability with a specific reference toxicant for each method?			
Does the laboratory produce test results that meet test acceptability criteria (such as greater than 80% survival in the control) as specified in the specific test method			
Is the intra-laboratory precision determined on an ongoing basis through the use of reference toxicant tests and plotted over time in quality control charts?	D.2.1.a.1.ii		

Based on: Rev. 9, July 2, 1998 Page 43 of 60



Delayant Aspect of Ctandards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Are the control charts plotted, as specified in the	D.2.1.a.1.ii		
test methods, as point estimate values, such as			
EC25 for chronic tests and LC 50 for acute tests?			
Is the frequency of reference toxicant testing	D.2.1.a.2		
compliant with the EPA or state permitting			
authority requirements?			
Are the reference toxicant or dilution series	D.2.1.a.3		
requirements for a particular test, as identified by			
the state or permitting authority followed?			
Is the test acceptability criteria calculated as	D.2.1.a.4		
specified in the test method?			
Is the test acceptability within the method	D.2.1.a.4		
specified requirements for performing toxicity?			
Is the test acceptability criteria achieved for both	D.2.1.a.4		
the reference toxicant and effluent test? (Example			
of test acceptable criteria, the chronic			
Ceriodaphnia test, requires 80% or greater			
survival and an average 15 young per female in			
the controls)			
Does the control population of Ceriodaphnia	D.2.1.a.4.i		
contain no more than 20% males?			
Is an individual test conditionally acceptable if	D.2.1.a.4.ii		
temperature, dissolved oxygen, pH and other			
specified conditions fall outside specifications?			
Is the conditionally acceptable test based on the	D.2.1.a.4.ii		
experience and professional judgement of the			
technical employee and the permitting authority?			
Are the controls, brine control or dilution water	D.2.1.b		
standards for the use, type and frequency of			
testing performed as specified by the methods			
and by permit?			
If the Dunnett's procedure used to calculate the	D.2.4.a		
minimum significant difference (MSD), is the MSD			
calculated using the formula specified by the EPA			
method?			
Is the MSD reported with the test results?	D.2.4.a		
Are the confidence intervals reported as a	D.2.4.c		
measure of the precision around the point			
estimate value (LCp, ICp, or ECp)?			



Delevent Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Is the MSD calculated and reported for chronic endpoints?	D.2.4.d		
Are the confidence intervals reported as a measure of the precision around the point estimate value for chronic testing?	D.2.4.d		
Is a minimum of four replicates per treatment performed so that either parametric or non-parametric tests can be conducted in order to calculate a reliable MSD?	D.2.4.d		
Are the methods of data analysis and endpoints specified by language in the permit or, by the EPA methods manuals for Whole Effluent Toxicity?	D.2.5.a		
Is the data plotted in the form of a curve relating to the dose if chemical to cumulative percentage of test organisms demonstrating a response such as death?	D.2.5.b		
Is the grade of all reagents used in Whole Effluent Toxicity tests as specified in the method?	D.2.6.a		
Are all reference standards prepared from analytical reagent grade or better chemicals?	D.2.6.a		
Is the preparation of all standards and reference toxicants documented?	D.2.6.a		
Are all standards and reagents associated with chemical measurements used in whole effluent toxicity, such as dissolved oxygen, pH or specific conductance documented? (Note: requirements are found in D.1 Chemical Testing)	D.2.6.b		
If closed refrigerator-sized incubators are used, are culturing and testing of organisms separated to avoid loss of cultures due to cross-contamination?	D.2.8.a		
Does the laboratory or a contracted outside expert positively identify test organisms to species on an annual basis?	D.2.8.b		
Are the taxonomic reference (citation and page(s)) and the names(s) of the taxonomic expert(s) on file at the laboratory?	D.2.8.b		

Based on: Rev. 9, July 2, 1998 Page 45 of 60



Delevent Aspect of Standards	Document I	Reference	Commente
Relevant Aspect of Standards	NELAC	Lab	Comments
Are instruments used for routine measurements of chemical and physical parameters such as pH, DO, conductivity, salinity, alkalinity, hardness, chlorine, and weight calibrated, and/or standardized per manufacturer's instructions and Appendix D.1 of the standard?	D.2.8.c		
Are all chemical and physical measurements and calibrations documented?	D.2.8.c		
Is all support equipment maintained in proper working order and records of all activities including service calls kept?	D.2.8.c 5.9.4.2.1.a		
Is all support equipment calibrated annually, using NIST traceable references when available, over the entire range in which the equipment is used?	D.2.8.c 5.9.4.2.1.b		
Are the results of support equipment calibration within ± the manufacturer's stated sensitivity?	D.2.8.c 5.9.4.2.1.b		
Is support equipment removed from service until repaired; or is deviation curve prepared and all measurements corrected for the deviation when the calibration is not within acceptance limits?	D.2.8.c 5.9.4.2.1.b		
Are all measurements recorded and maintained for the deviation curve?	D.2.8.c 5.9.4.2.1.b		
Prior to use on each working day, are balances, ovens, refrigerators, freezers, incubators and water baths checked with NIST traceable references (where possible) in the expected use range?	D.2.8.c 5.9.4.2.1.c		
Is additional monitoring as prescribed by the method performed for any device that is used in a critical test (such as incubators or water baths)?	D.2.8.c 5.9.4.2.1.c		
Is the acceptability for use or continued use according to manufacturer requirements if not included in the method?	D.2.8.c 5.9.4.2.1.c		
Is the test temperature maintained as specified in the methods manuals?	D.2.8.d		
Is the average daily temperature of the test solutions maintained within 1°C of the selected test temperature, for the duration of the test?	D.2.8.d		



Delevent Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Is the minimum frequency of measurement once	D.2.8.d		
per 24-hour period for static test?			
Is the test temperature for continuous flow toxicity	D.2.8.d		
tests recorded and monitored continuously?			
Is the water used for culturing and testing	D.2.8.e		
analyzed for toxic metals and organics annually			
or whenever the minimum acceptability criteria for control survival, growth or reproduction is not met			
and no other cause, such as contaminated			
glassware or poor stock, is identified?			
Are the method specified analytes and	D.2.8.e		
concentration levels followed?	D121010		
Are new batches of food or food combinations	D.2.8.f		
with a new lot of any ingredient used for culturing			
and testing analyzed for toxic organics and			
metals?			
Is the food used only if the following criteria are	D.2.8.f		
met?			
• Total organic chlorine < 0.15 μg/g wet weight,			
Total concentration of organochlorine Total concentration of organochlorine Total concentration of organochlorine Total concentration of organochlorine			
pesticides plus PCBs ≤ 0.30 ug/g wet weight			
 Toxic metals < 20μg/g wet weight Is the test chamber size and test solution volume 	D.2.8.g		
as specified in the methods manuals?	D.2.0.y		
Are the test organisms fed the quantity of food,	D.2.8.h		
type of food and at the frequency specified in the			
methods manuals?			
Is the light intensity and photoperiod maintained	D.2.8.i		
as specified in the methods manuals.			
Are measurements made and recorded on a	D.2.8.i		
yearly basis and the photoperiod documented at			
least quarterly?			
For algal tests, is the light intensity measured and	D.2.8.i		
recorded at the start of each test?	D 2 0 '		
As a minimum, during chronic testing are the DO	D.2.8.j		
and pH measured daily in at least one replicate of			
each concentration? (Note: DO may be measured in new solutions prior to organism transfer, in old			
solutions after organism transfer, or both.)			
Solutions after organism transfer, or both.	<u> </u>		



Delevient Aspect of Standards	Document I	Reference	Commonto
Relevant Aspect of Standards	NELAC	Lab	Comments
Are all cultures used for testing maintained as	D.2.8.k		
specified in the methods manuals?			
Are the age and the age range of the test	D.2.8.I		
organisms specified in the manuals?			
Is the maximum holding time (lapsed time from	D.2.8.m		
sample collection to first use in a test) 36 hours			
unless permission of the permitting authority has			
been received?			
Are all samples chilled to 4°C during or	D.2.8.n		
immediately after collection and maintained at 0.1			
to 6°C?			
Is the arrival temperature no greater than 6°C.	D.2.8.n		
(Note: Samples that are hand delivered to the			
laboratory immediately after collection (i.e., within			
1 hour) may not meet the laboratory temperature			
acceptance criteria. In these cases, the			
laboratory may accept the samples if there is			
evidence (such as arrival on ice) that the chilling process has begun.)			
Are organisms obtained from an outside source	D.2.8.0		
from the same batch?	D.2.0.0		
5. APPENDIX D - Microbiology Testing Det	<u>l</u> tailed Method	Doviou	
Method Number:	laneu Meniou	Keview	
SOP Number:			
Rev.:			
SOP date:			
Personnel records observed:			
i cisoffici fecolus observeu.			
Data records observed:			
Do the controlsused to demonstrate thatt the	D.3.1.a		
cultured samples have not been contaminated			
through sample handling/preparation or			
envivonmental exposure include sterility checks			
of media and blanks such as the incubation of			
filtration blanks?			
Are all blanks and uninoculated controls specified	D.3.1.a.1		
by the method prepared and analyzed at the			
frequency stated in the method?			

Based on: Rev. 9, July 2, 1998 Page 48 of 60



Delevent Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Is a minimum of one uninoculated control	D.3.1.a.2		
prepared and analyzed?	D 0.1 0		
When the same equipment is used to prepare	D.3.1.a.2		
multiple samples for incubation (such as a filtration unit) does the laboratory prepare a series			
of blanks using the equipment? (Note: At least			
one beginning and ending control shall be			
prepared, with additional controls inserted after			
every 10 samples.)			
Is each lot of media tested on a monthly basis	D.3.1.b,		
with at least one pure culture of a known positive	D.3.4,		
reaction (positive control) that is included with the	D.3.6.e		
sample test batch?			
Are at least 5% of the suspected positive samples analyzed in duplicate?	D.3.2.a		
In laboratories with more than one analyst	D.3.2.a		
performs the testing, does each analyst make	D.3.2.u		
parallel analyses on at least one positive sample			
per month?			
Where possible, does the laboratory participate	D.3.2.b		
in, or conduct collaborative trails, proficiency	D.3.3.b		
testing or inter-laboratory comparisons, either			
formal or informal?	D 0 0		
Does the laboratory establish a set of acceptance	D.3.3.a		
criteria for the performance characteristics			
through the use of method validation? (Note: this is not required if performance characteristics are			
specified in the reference method.)			
Do these criteria demonstrate that the method	D.3.3.a		
provides a correct/expected result with respect to	D.3.3.u		
specified limits of detection, selectivity,			
repeatability, sensitivity and reproductivity?			
Does the laboratory demonstrate proficiency with	D.3.3.a.1		
the method prior to use?			
Are qualitative microbiological test method	D.3.3.a.2		
(presence/absence) validated by estimating if			
possible the specificity and reproducibility.			
Are differences due to matrices taken into	D.3.3.a.2		
account when testing different sample types			



Delevent Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Is the validation of microbiological test methods performed under the same conditions as those of a real assay? (Note: This can be achieved by using a combination of naturally contaminated products and spiked products.)	D.3.3.a.3		
Are all validation data recorded and stored at least as long as the method is in force, or if withdrawn from active use, for at least 5 years past the date of last use?	D.3.3.a.4		
Are the calculations, data reduction and statistical interpretations specified by each method followed?	D.3.5.a		
Where the method specifies colony counts, such as membrane filter or colony counting, is the ability of individual analysts to count colonies verified at least once per month, by having two or more analysts count colonies from the same plate?	D.3.5.b		
Are reagents and commercial dehydrated powders consumed within the shelf life of the product?	D.3.6.b		
Does the laboratory retain all manufacturer supplied "quality specification statements"?	D.3.6.b		
Is distilled water, deionized water or reverse osmosis produced water free from bactericidal and inhibitory substances used in the preparation of media solutions and buffers?	D.3.6.c		
Where required by the method, is the quality of the water (such as pH, chlorine residual, specific conductance or metals) monitored at the specified frequency and evaluated according to the stated standards?	D.3.6.c		
Are records maintained on all laboratory reagent water monitoring activities?	D.3.6.c		
Are media, solutions and reagents prepared, used and stored according to a documented procedure following the manufacturer's/author's instructions?	D.3.6.d		

Based on: Rev. 9, July 2, 1998 Page 50 of 60



Relevant Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Is selective media checked to ensure they suppress the growth of non-target organisms, if possible using a quantitative procedure, where a known (often low) number of relevant organisms are inoculated into the medium under test and the recovery evaluated.)	D.3.6.e		
Is each lot of laboratory detergent checked to ensure that residues from the detergent do not inhibit or promote growth of microorganisms using a test such as the inhibitory residue test.	D.3.6.f		
Are all confirmation/verification tests specified by the method performed according to method protocols?	D.3.7.a		
In order to demonstrate traceability and selectivity, does the laboratory use reference cultures of microorganisms obtained from a recognized national collection or an organization recognized by the assessor body?	D.3.7.b		
Are reference cultures subcultured once to provide reference stocks? Is appropriate purity and biochemical checks made and documented?	D.3.7.b.1		
Are the reference stocks preserved by a technique that maintains the desired characteristics of the strains? (Examples of such methods are freeze-drying, liquid nitrogen storage and deep-freezing methods.)	D.3.7.b.1		
Are reference stocks used to prepare working stocks for routine work?	D.3.7.b.1		
Are reference stocks that are thawed not refrozen and not re-used?	D.3.7.b.1		
Are bacterial working stocks not sub-cultured under normal conditions?	D.3.7.b.2		

Based on: Rev. 9, July 2, 1998 Page 51 of 60



Delevent Aspect of Standards	Document Reference		Commente
Relevant Aspect of Standards	NELAC	Lab	Comments
Are working stocks sub-cultured up to a defined number of subcultures when: i. it is required by standard methods, or ii. laboratories can provide documentary evidence demonstrating that there has been no loss of viability, no changes in biochemical activity and/or no change in morphology.	D.3.7.b.2		
Are working stocks not sub-cultured to replace reference stocks?	D.3.7.b.3		
Does the laboratory trend the levels of contamination appropriate to the type of testing being carried out?	D.3.8.a		
Are acceptable background counts determined and documented procedures followed to deal with situations where limits are exceeded?	D.3.8.a		
Are wooden surfaces of fixtures and fittings adequately sealed?	D.3.8.b		
Are all surfaces non-absorbents and easy to clean and disinfect and are measures taken to avoid accumulation of dust?	D.3.8.b		
Are the temperature measurement devices the appropriate quality to achieve the specification in the test method? (See 5.9.4.2.1 for details)	D.3.8.c.1		
Is the device's temperature calibration traceable to national or international standards?	D.3.8.c.1		
Are the graduations of the temperature measuring devices appropriate for the required accuracy of measurement?	D.3.8.c.1		
Temperature measuring devices are calibrated against national or international standards for temperature at least annually.	D.3.8.c.1		
Is the stability of temperature, uniformity of temperature distribution and time required to achieve equilibrium conditions in incubators, water baths, ovens and temperature-controlled rooms established?	D.3.8.c.2		

Based on: Rev. 9, July 2, 1998 Page 52 of 60



Delevant Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Is the performance of each autoclave initially	D.3.8.d.1		
evaluated by establishing its functional			
properties?			
Are the autoclave(s) capable of meeting specified	D.3.8.d.1		
temperature tolerances? (Pressure cookers fitted			
only with a pressure gauge are not recommended			
for sterilization of media or decontamination of			
wastes.)	D 2 0 4 2		
Are records of autoclave operations including	D.3.8.d.2		
temperature and time maintained for each cycle?	D 3 0 4 3		
Is acceptance/rejection criteria established and	D.3.8.d.2		
used to evaluate the autoclave efficiency and effectiveness?			
Are regular checks of volumetric equipment	D.3.8.e		
performed and documented?	D.3.6.E		
Is calibration of support equipment (conductivity	D.3.8.f		
meters, oxygen meters, pH meters, hygrometers,	D.3.0.1		
and other similar measurement instruments)			
according to the method specified requirements?			
Are mechanical timers checked agaist electronic	D.3.8.f		
timing devices to ensure accurate timing?			
5. APPENDIX D - Radiochemical Analysis	Detailed Meth	od Review	
Method Number:			
SOP Number:			
Rev.:			
SOP date:			
Personnel records observed:			
Data records observed:			
Does the radiochemical analytical laboratory	5.10.1.1		
maintain a Quality Assurance (QA) program that			
assures the validity of analytical measurements			
made by the laboratory?			
Are the QA activities of the laboratory described	5.10.1.1		
in the laboratory's Quality Manual and outlined in			
the Standard Operating Procedures (SOPs)?			

Based on: Rev. 9, July 2, 1998 Page 53 of 60



Delevent Aspect of Standards	Document I	Reference	Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Is corrective actions taken by the laboratory documented when the analysis results are outside of the predetermined control limits for that parameter?	D.4.1.a		
Are these control limits, and the required frequency of use for each type of QC sample, defined in either the laboratory's QA Plan or the individual SOPs?	D.4.1.a		
Are method blanks, analyzed at a frequency of one per preparation batch, used to assess batch acceptance.	D.4.1.a		
In the case of gamma spectrometry, is the method blank prepared from a similar counting geometry that is empty or filled to similar volume with ASTM Type II water used to partially simulate gamma attenuation due to a sample matrix?	D.4.1.b		
There is be no subtraction of the required method blank result from the sample results in the associated preparation or analytical batch.	D.4.1.c		
Does the method blank acceptance criteria address the presumed aliquot size on which the method blank result is calculated and the manner in which the method blank result is compared to sample results of differing aliquot size?	D.4.1.d		
Is a Laboratory Control Samples analyzed at a frequency of one per preparation batch and the results of this analysis used as one of the quality control measures to be used to assess batch acceptance?	D.4.2.a		
Is the laboratory control sample result assessed against the specific acceptance criteria] specified in the laboratory method manual?	D.4.2.a		
When the specified laboratory control sample acceptance criteria is not met is the specified corrective action and contingencies followed?	D.4.2.a		
Is the occurrence of a failed laboratory control sample acceptance criteria and the actions taken noted in the laboratory report?	D.4.2.a		

Based on: Rev. 9, July 2, 1998 Page 54 of 60



Delevent Aspect of Standards	Document I	Reference	Commente
Relevant Aspect of Standards	NELAC	Lab	Comments
Is a Matrix Spike analyzed at a frequency of one per preparation batch for those methods which do not utilize an internal standard or carrier and for which there is a physical or chemical separation process and where there is sufficient sample to do so?	D.4.2.b		
Are the results of the analysis of the matrix spike one of the quality control measures used to assess batch acceptance?	D.4.2.b		
Is the matrix spike result assessed against the specific acceptance criteria specified in the laboratory method manual?	D.4.2.b		
When the specified matrix spike acceptance criteria is not met, is the specified corrective action and contingencies followed?	D.4.2.b		
Is the occurrence of a failed matrix spike acceptance criteria and the actions taken noted in the laboratory report?	D.4.2.b		
Is the lack of sufficient sample aliquot size to perform a replicate analysis noted in the laboratory report?	D.4.2.b		
Is the activity of the laboratory control sample and matrix spike analyte(s) greater than ten times and less than one hundred times the detection limit?	D.4.2.c		
Are the laboratory standards used to prepare the laboratory control sample and matrix spike from a source independent of the laboratory standards used for instrument calibration?	D.4.2.d		
When a radiochemical method, other than gamma spectroscopy, has more than one reportable analyte isotope (e.g. isotopic uranium: U-234, -235, and -238) is one of the analyte isotopes included in the laboratory control or matrix spike sample at the indicated activity level?	D.4.2.e		
Where more than one analyte isotope is present above the specified activity level is each assessed against the specified acceptance criteria?	D.4.2.e		

Based on: Rev. 9, July 2, 1998 Page 55 of 60



Delevient Aspect of Ctandards	Document I	Reference	Commonto
Relevant Aspect of Standards	NELAC	Lab	Comments
Where gamma spectrometry is used to identify and quantitate more than one analyte isotope does the laboratory control sample and matrix spike contain isotopes that represent the low (e.g. americium-241), medium (e.g. cesium-137) and high (e.g. cobalt-60) energy range of the analyzed gamma spectra? (Tthe isotopes need not exactly bracket the calibrated energy range or the range over which isotopes are identified and quantitated.)	D.4.2.f		
Are replicates analyzed at a frequency of one per preparation batch where there is sufficient sample to do so?	D.4.3.a		
Are the results of replicate analysis one of the quality control measures used to assess batch acceptance?	D.4.3.a		
Is the replicate result assessed against the specific acceptance criteria specified in the laboratory method manual?	D.4.3.a		
When the specified replicate acceptance criteria is not met, are the specified corrective action and contingencies followed?	D.4.3.a		
Is the occurrence of a failed replicate acceptance criteria and the actions noted in the laboratory report?	D.4.3.a		
For those methods that utilize a tracer (i.e. internal standard), is each sample result associated tracer recovery calculated and reported?	D.4.4.a		
Is the tracer recovery for each sample results one of the quality control measures used to assess the associated sample result acceptance?	D.4.4.a		
Is the tracer recovery assessed against the specific acceptance criteria specified in the laboratory method manual?	D.4.4.a		
When the specified tracer recovery acceptance criteria is not met, are the specified corrective action and contingencies followed?	D.4.4.a		
Is the occurrence of a failed tracer recovery acceptance criteria and the actions taken noted in the laboratory report?	D.4.4.a		
For those methods that utilize a carrier (i.e. internal standard), is each sample associated carrier recovery calculated and reported?	D.4.4.b		

Based on: Rev. 9, July 2, 1998 Page 56 of 60



Delevent Aspeat of Standards	Document I	cument Reference Common	
Relevant Aspect of Standards	NELAC	Lab	Comments
Is the carrier recovery for each sample one of the	D.4.4.b		
quality control measures used to assess the			
associated sample result acceptance?			
Is the carrier recovery assessed against the specific acceptance criteria specified in the laboratory method manual?	D.4.4.b		
When the specified carrier recovery acceptance criteria is not met, is the specified corrective action and contingencies followed?	D.4.4.b		
Is the occurrence of a failed carrier recovery acceptance criteria and the actions taken in the laboratory report?	D.4.4.b		
The Initial Demonstration of is performed initially (prior to the analysis of any samples) and with a significant change in instrument type, personnel or method?	D.4.5.a, 5.10.2.1.a		
Are the results of proficiency test sample analysis used by the laboratory to evaluate the ability of the laboratory to produce accurate data?	D.4.5.b		
Do the providers of such proficiency test samples conform to the requirements of ANSI N42.22?	D.4.5.b		
For those radiochemical methods that may require multiple standards for initial calibration (e.g. gas-proportional counting and liquid scintillation counting), is the required number of standards addressed in the laboratory method manual] if not addressed in the method?	D.4.6.a		
Where linear regression is used to fit standard response or calibration standard results to a calibration curve is the correlation coefficient determined?	D.4.6.b		
Where non-linear regression is used to fit standard response or calibration standard results to a calibration curve is the correlation coefficient determined?	D.4.6.ba		
When the laboratory control sample is used as the initial ca;libration and continuing calibration standard, is the acceptance criteria the same as specifies for the LCS?	D.4.6.d		
Are background calibration measurements made on a regular basis and monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required data quality objectives?	D.4.6.e		



Delevent Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Are backgraound calibration measurements subtracted from the total measured activity in the determination of the sample activity?	D.4.6.e		
For gamma spectroscopy systems, are background calibration measurements performed on at least a monthly basis?	D.4.6.e		
For alpha spectroscopy systems, are background calibration measurements performed on at least a monthly basis?	D.4.6.e		
For gas-proportional and scintillation counters, are background calibration measurements performed on a day of use basis?	D.4.6.e		
Is Instrument calibration performed with reference standards as defined in section D.4.9.a?	D.4.6.f		
Do the standards have the same general characteristics (i.e. geometry, homogeneity, density, etc.) as the associated samples?	D.4.6.f		
Is the frequency of calibration addressed in the laboratory method manual if not addressed in the method?	D.4.6.g		
Is a specific frequency (e.g. monthly) or observations from the associated control or tolerance chart, usedas the basis for calibration specified?	D.4.6.g		
Does the laboratory have the ability to trace all sources of method uncertainties and their propagation to reported results?	D.4.8.b		
Is the ISO "Guide to the Expression of Uncertainty in Measurement" and/or the NIST Technical Note 1297 on "Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results" used to trace all sources of method uncertainties and their propagation to reported results?	D.4.8.b		
Are the reference standards that are obtained from the National Institute of Standards and Technology (NIST), EPA, or suppliers who participate in supplying NIST standards or NIST traceable radionuclides?	D.4.9.a.1		
Are any reference standards purchased outside the United States traceable back to each country's national standards laboratory?	D.4.9.a.1		
Do commercial suppliers of reference standards conform to ANSI N42.22 to assure the quality of their products?	D.4.9.a.1		

Based on: Rev. 9, July 2, 1998 Page 58 of 60



Delevent Aspect of Standards	Polovant Aspect of Standards Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
Are reference standards accompanied with a certificate of calibration whose content is as described in ANSI N42.22 - 1995, Section 8, Certificates?	D.4.9.a.2		
Does the laboratory consult with the supplier if the lab's verification of the activity of the reference traceable standard indicates a noticeable deviation from the certified value?	D.4.9.a.3		
The laboratory does not use a value other than the decay corrected certified value?	D.4.9.a.3		
Are all reagents used analytical reagent grade or better?	D.4.9.b		
Does the laboratory establish and adhere to written procedures to minimize the possibility of cross-contamination between samples.	D.4.10.a		
Are instrument performance checks using appropriate check sources performed on a regular basis and monitored with control charts or tolerance charts to ensure that the instrument is operating properly and that the calibration has not changed?	D.4.10.b		
Is the same check source used in the preparation of the tolerance chart or control chart at the time of calibration used in the performance checks of the instrument?	D.4.10.b		
Does the check sources provide adequate counting statistics for a relatively short count time?	D.4.10.b		
Is the source sealed or encapsulated to prevent loss of activity and contamination of the instrument and laboratory personnel?	D.4.10.b		
For alpha and gamma spectroscopy systems, do the instrument performance checks include checks on the counting efficiency and the relationship between channel number and alpha or gamma ray energy?	D.4.10.b		
For gamma spectroscopy systems, are the performance checks for efficiency and energy calibration performed on a day of use basis along with performance checks on peak resolution?	D.4.10.b.1		
For alpha spectroscopy systems, are the performance check for energy calibration performed on a day of use basis and the performance check for counting efficiency shall be performed on at least a monthly basis?	D.4.10.b.2		

Based on: Rev. 9, July 2, 1998 Page 59 of 60



Relevant Aspect of Standards	Document Reference		Comments
Relevant Aspect of Standards	NELAC	Lab	Comments
For gas-proportional and scintillation counters, is the performance checks for counting efficiency shall be performed on a day of use basis?	D.4.10.b.3		

Based on: Rev. 9, July 2, 1998 Page 60 of 60